# The Pharmaceutical Drug Racket

## Corporate Crime in the Pharmaceutical Industry

*Part Two*

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The sordid behaviour of today's pharmaceutical corporations has been further demonstrated by Dr John Braithwaite, now a Trade Practices Commissioner, in his devastating exposé, *Corporate Crime in the Pharmaceutical Industry* [1](1984).

> International bribery and corruption, fraud in the testing of drugs, criminal negligence in the unsafe manufacture of drugs—the pharmaceutical industry has a worse record of law-breaking than any other industry.

Describing many examples of corporate crime, which shows the depth and seriousness of the crime problem in the pharmaceutical industry, Dr Braithwaite's revealing study is based on extensive international research, including interviews of 131 senior executives of pharmaceutical companies in the United States, the United Kingdom, Australia, Mexico and Guatemala.

The book shows how pharmaceutical multinationals defy the intent of laws regulating safety of drugs by bribery, false advertising, fraud in the safety testing of drugs, unsafe manufacturing processes, smuggling and international law evasion strategies.

At the time of researching the subject, Braithwaite was a research criminologist at the Australian Institute of Criminology and a Fulbright Fellow affiliated to the University of California, Irvine, and the United Nations Center on Transnational Corporations.

### Fraud in Drug Testing

"Data fabrication is so widespread," says Dr Braithwaite, "that it is called 'making' in the Japanese pharmaceutical industry, 'graphiting' or 'dry labelling' in the United States." He further states:

> Pharmaceutical companies face great temptations to mislead health authorities about the safety of their products. It is a make or break industry—many companies get virtually all their profits from just two or three therapeutic winners.
>
> Most of the data that the Australian Drug Evaluation Committee relies upon in deciding questions of safety and efficacy is data from other countries, particularly the US. **Inquiries into scientific fraud in the US have shown there is a substantial problem of fraud in safety testing of drugs in the US, just as has been documented in Japan.** [Emphasis added.][2]

In his book Braithwaite cited former FDA Commissioner Goddard expressing his concerns over research dishonesty at a Pharmaceutical Manufacturers Association Meeting in 1966:

> I have been shocked at the materials that come in. In addition to the problem of quality, there is the problem of dishonesty in the investigational new drug usage. I will admit there are grey areas in the IND situation, but the conscious withholding of unfavourable animal clinical data is not a grey matter. The deliberate choice of clinical investigators known to be more concerned about industry friendships than in developing good data is not a grey matter. The planting in journals of articles that begin to commercialize what is still an investigational new drug is not a grey matter area. These actions run counter to the law and the efforts governing drug industry [*sic*!]

Goddard's immediate successor at the FDA, Dr Ley, spoke before the US Senate hearings of a spot check that showed up the case of an assistant professor of medicine who had reputedly tested 24 drugs for 9 different companies. "Patients who died while on clinical trials were not reported to the sponsor," an audit revealed. "Dead people were listed as subjects of testing. People reported as subjects of testing were not in the hospital at the time of tests. Patient consent forms bore dates indicating they were signed by the subjects after the subjects died."[4]

Another audit looked at a commercial drug-testing firm that had apparently worked on 82 drugs and 28 sponsors:

> Patients who died, left the hospital or dropped out of the study were replaced by other patients in the tests without notification in the records. Forty-one patients reported as participating in studies were dead or not in the hospital during the studies... Record-keeping, supervision and observation of patients in general were grossly inadequate.[5]

Between 1977 and 1980 the FDA have discovered 62 doctors who had submitted manipulated or downright falsified clinical data.[6] A study conducted by the FDA has revealed that one in five doctors investigated, who carry out field research of new drugs, had invented the data they sent to the drug companies, and pocketed the fees.[7]

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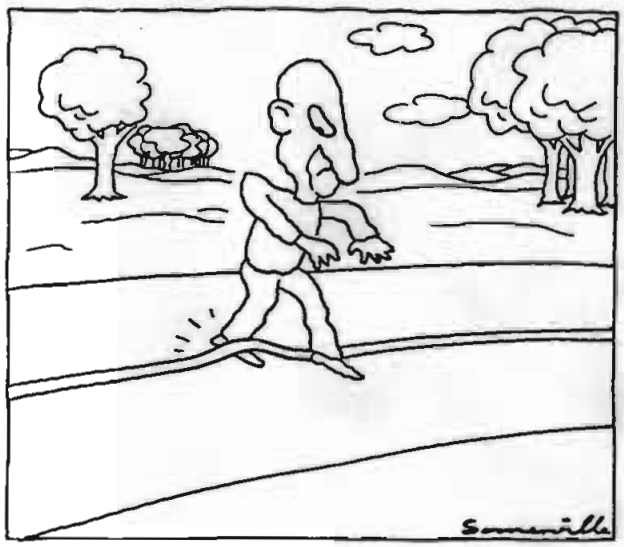
Citing case examples, Dr Braithwaite states:

> The problem is that most fraud in clinical trials is unlikely to even be detected. Most cases which do come to public attention only do so because of extraordinary carelessness by the criminal physician...[8]

According to Dr Judith Jones, Director of the Division of Drug Experience at the FDA, if the data obtained by a clinician proves unsatisfactory towards the drug being investigated, it is quite in order for the company to continue trials elsewhere until satisfactory results and testimonials are achieved. Unfavourable results are very rarely published and clinicians are pressured into keeping quiet about such data.[9]

It is very easy for the drug company to arrange appropriate clinical trials by approaching a sympathetic clinician to produce the desired results that would assist the intended application of the drug.[10] The incentive for clinical investigators to fabricate data is enormous. **As much as $1,000 per subject is paid by American companies, which enables some doctors to earn up to $1 million a year from drug research,**[11] and investigating clinicians know all too well that if they don't produce the desired data, the loss of future work is inevitable.



### University Scientists—The More Than Willing Pawns

Braithwaite cited an FDA survey of safety testing violations that have shown that university laboratories had the worst record for violations than all other laboratories in the survey.[12] Braithwaite writes:

> As one would predict from the foregoing discussion of how contract labs can be used by sponsors to abrogate responsibility for quality research, contract labs were found to have a worse record of GLP [Good Laboratory Practices] violations than sponsor labs. The worst record of all, however, was with university laboratories. One must be extremely cautious about this finding since there were only five university laboratories in the study. Nevertheless, it must undermine any automatic assumption that university researchers, with their supposed detachment from the profit motive, are unlikely to cut corners on research standards.[13]

### Inappropriate Clinical Trials

Even if data obtained from clinical trials is not falsified, it is of little worth, because they are not performed appropriately. Trials involve relatively small numbers of people; so many harmful effects of a new drug appear only when it has been marketed and widely used.

Furthermore, the subjects taking part in the trial usually do not represent those who will use the drug after its approval. Very young or elderly people, women of child-bearing age and people with liver or kidney disease are usually not included in clinical trials, although such people may be given the drug after it is marketed. Also, optimal dosages for adults are calculated on the basis of what is most effective for an average-size adult. Many adults differ from this average, and about 45 per cent of ordinary adults are probably going to respond atypically to some classes of drugs.[14]

### Drug Companies Concealing and Misrepresenting Dangerous Drug Effects

Dr Braithwaite cited a number of cases where drug companies concealed and misrepresented dangerous effects of drugs noted by their own investigators. Braithwaite writes:

> In 1959 Wallace and Tiernan put a new tranquilliser, Dornwal, on the market despite the strenuous objections of its own medical director. Other company experts warned that Dornwal could cause serious and possibly fatal blood damage. They were right. Wallace and Tiernan failed to send to the FDA reports of side-effects which induced nine cases of bone marrow disease and three deaths from using the drug (Johnson, 1976)[15a]...
>
> One could list a number of similar types of cases. Johnson and Johnson's subsidiary, McNeil Laboratories, was denounced by the FDA for concealing information on side-effects of Flexin which according to Johnson (1976) included the drug being associated with 15 deaths from liver damage. **Such more blatant cases are merely the tip of an iceberg of selective misinformation.**
>
> The most dramatic recent case has been the disclosures in the British Parliament and US Congress that Eli Lilly and Co. knew of the dangers of Opren, an anti-arthritic drug associated with 74 deaths in Britain alone, 15 months before the drug was withdrawn (*Sunday Times*, 27 February 1983)...
>
> The problem is not restricted to Anglo-Saxon countries. In November 1982, a Japanese company, Nippon Chemiphar, admitted to presenting bogus data to the Japanese Government with its application to market a pain-killer and anti-inflamma-

tion drug under the brand name of Norvedan. The company submitted cooked up data to the Government in the name of Dr Harcio Sampei, chief of plastic surgery at Nippon University. The good doctor had accepted 2.4 million Yen in cash from the company in return for permission to use his name. More disturbing are similar allegations on another Nippon Chemiphar product. The company denies cooking data on this second product. But the worrying aspect of the second scandal is that a former company researcher claims to have submitted a written report alleging fraud in drug testing by Nippon Chemiphar to the Japanese Health and Welfare Ministry; Ministry officials, he alleges, chose to ignore the report (*Japan Times*, 23, 24, 25 November 1982). [Emphasis added.][15]

### In Whose Interests Are Drugs Tested?

The testing procedures of drugs are primarily performed to ensure the approval and marketing of these substances; despite the fact they are usually unsafe and ineffective. If drug companies were truly ethical and responsible, the vast majority of drugs would not have been allowed on the market in the first place.

West Germany's prestigious weekly, *Der Spiegel* (24 June 1985), carried a most revealing article titled, "How The Pharmaceutical Industry Bought Bonn". The article, which featured on the front page and covered several pages, contributes to the real motives behind drug testing. In essence, the article could just as well apply to the United States, Britain and most other industrial nations. The following is a brief excerpt:

> As a rule, the drug companies didn't pour millions into the coffers of the political parties, but gave money to individual politicians and public officials selected among those that determine the health policy. With the help of congressmen in their employ, they acquired uniquely favorable marketing conditions that would insure them durable profits. The pharmaceutical industry, which is worth billions, has bought up, as it were, the legislature, as the uncovered documents reveal...
>
> **The approval of drugs should henceforth depend on two conditions: evidence of their 'efficacity' and of their 'innocuity', provided by chemo-physical tests, animal experiments, and clinical assays and opinions.** [Emphasis added.]

**... many of the most common or life-threatening side-effects cannot be predicted by animal tests.**

**... animals cannot let the experimenter know if they are suffering from headache, amnesia, nausea, depression and other psychological disturbances.**

Many of the politicians and public officials who contributed to the acceptance of these guidelines were named in the article, and the bribes they pocketed were itemised.

### Fraudulent Animal Testing

The most blatantly fraudulent procedure of drug testing is the testing of these substances using animal models—a practice often termed 'vivisection'. To begin with, many of the most common or life-threatening side-effects cannot be predicted by animal tests. For instance, animals cannot let the experimenter know if they are suffering from headache, amnesia, nausea, depression and other psychological disturbances. Allergic reactions, some blood disorders, skin lesions and many central nervous system effects are even more serious examples that cannot be demonstrated by animal models.[16]

According to one of the world's best known toxicologists, Professor Gerhardt Zbinden, from Zurich's Institute of Toxicology, "Most adverse reactions that occur in man cannot be demonstrated, anticipated or avoided by the routine subacute and chronic toxicity experiment."[17] Professor Zbinden has shown that of the 45 most common adverse reactions only three may possibly be predicted, and of the remaining 42, "only in exceptional cases can they be predicted from routine toxicologic tests".[18]

### Species Differences

Apart from the effects that cannot be demonstrated in animals, another very fundamental problem exists with testing substances using animals. Each individual species of animal has a unique genetic make-up. Any genetic differences predetermine massive variations in histology (structure, composition and function of tissues), biochemistry (chemistry of living organisms), morphology (structure of organisms), physiology (function of living organisms), and other species characteristics. Because each animal species is different, substances that are tested on them for 'safety' and 'effectiveness' will have a different effect on each individual species. This has been amply demonstrated by Professor Pietro Croce, former animal experimenter, and world-renowned author and medical researcher, in his revealing treatise, *Vivisection or Science—A Choice to Make*[19] (1991).

Morphine sends cats into a frenzy of excitement, yet it calms and anaesthetises humans. The amount of opium that can be eaten without discomfort by the hedgehog would keep the most hardened addict happy for a fortnight. Arsenic kills humans but is harmless to guinea-pigs, chickens and monkeys. Chloroform, used successfully for decades in human surgery, is poisonous for dogs. Digitalis, which dangerously raises the blood pressure of dogs, is used to lower blood pressure for humans.[20] The list can be lengthened at will, but these few examples should be sufficient to demonstrate that there could not be a more unreliable test for new drugs than animal experimentation.

There are five basic stages in which a drug has an effect when taken internally. These are: absorption into the bloodstream, distribution to the site of action, mechanism of action, metabolism, and excretion. Considering that people of different sexes, ages, health and genetic make-up may react quite differently, it is obvious that other species often react very differently. Even a minor change, repeated at each stage, can accumulate, resulting in a major change of effect. One of the most important factors is the speed and pattern of metabolism, or the way in which a drug is broken down by the body.[21] Scientific reports show that variation in drug metabolism between species is the rule rather than the exception.[22,23]

Toxic drug effects not predicted by animal testing may be seen in people if their metabolism is slower, with the potentially dangerous result from longer exposure. The anti-inflammatory drugs phenylbutazone and oxyphenbutazone, which have been responsible for an estimated 10,000 deaths worldwide,[24] takes 72 hours for people to metabolise. However, phenylbutazone is metabolised by rhesus monkeys, dogs, rats and rabbits in eight, six, six, and three hours, respectively.[25] Oxyphenbutazone takes only half an hour for dogs to metabolise.[26]

Another fundamental problem that makes animal testing a flawed process concerns the etiology (cause) of the disease that the drug under test is supposed to treat. Because animals don't suffer the same diseases as humans, experimenters attempt to artificially recreate spontaneous human diseases (naturally occurring diseases that arise from within) in healthy animals, and then they use these 'models' to attempt to determine the efficacy (effectiveness) of the drug in question. This is totally illogical because the artificially recreated animal disease can in no way approximate a naturally occurring human disease (nor of the same animal species for that matter). Once a disease is 're-created', it is artificial and is no longer the original, natural disease. Sometimes it is possible to re-create some of the symptoms of the disease but never the disease itself. The only exception is infectious diseases, but animals do not get human infectious diseases and we do not get theirs.[27,28]

As well as the routine subacute and chronic toxicity tests (which involve poisoning by a substance being taken in normal quantities over a long period of time), drugs are also tested on animals for acute toxicity (poisoning due to a large amount of substance taken in a short period of time) and teratogenicity (ability to cause foetal malformations).

### Fraudulent Acute Toxicity Tests

The LD50 is an acute toxicity test designed to indicate the human lethal dose that results from accidental or intentional overdose. The

standard LD50 tests consist of forcing massive amounts of the test substance down the throats of a large number of animals to discover at what dosage-level about 50 per cent of them will die. Even if the substance is not poisonous to the animal, it will cause damaging effects by overpowering the animal's ability to cope with the sheer quantities.[29]

Most toxicologists and clinicians agree that these tests are scientifically indefensible. Professor Zbinden writes: "For the recognition of the symptomatology of acute poisoning in man, and for the determination of the human lethal dose, the LD50 in animals is of very little value."[30] D. Lorke, from the Institute of Toxicology, Bayer AG, Germany, states that "even if the LD50 could be measured exactly and reproducibly, the knowledge of its precise numerical value would barely be of practical importance, because an extrapolation from the experimental animals to man is hardly possible."[31]

Despite the fact that the these tests have no scientific validity, they are used as a crude index of acute toxicity, demanded by government regulations. According to one of Britain's largest contract laboratories, Huntingdon Research Centre, "Approximately 90 per cent of LD50 tests which are performed by this Contract Research Centre, and probably by others also, are purely to obtain a value for various legislative needs."[32]

### Fraudulent Teratogenic Tests

Supposedly to safeguard pregnant women from the exposure of potentially teratogenic drugs, these substances are tested on various species of pregnant animals before being marketed. However, these tests are also worthless, because as Dr Robert Sharpe explains in his book, *The Cruel Deception* (1988):

> In pregnant animals, differences in the physiological structure, function and biochemistry of the placenta aggravate the usual differences in metabolism, excretion, distribution and absorption that exists between species and make reliable predictions impossible.[33]

The ineffectiveness of the teratogenic tests is demonstrated by the fact that the malformations caused by thalidomide (a drug prescribed to pregnant women for morning sickness that caused over 10,000 grotesque birth deformities) proved very difficult to duplicate on animals, despite being tested on a large range of species. Writing in his book, *Drugs as Teratogens*, J. L. Schardein comments:

> In approximately 10 strains of rats, 15 strains of mice, 11 breeds of rabbit, two breeds of dogs, three strains of hamsters, eight species of primates and in other such varied species as cats, armadillos, guinea pigs, swine and ferrets in which thalidomide has been tested, teratogenic effects have been induced only occasionally.[34]

Further, medical historian, Hans Ruesch points out in his book, *Slaughter of the Innocent* (1991):

> Only when the white New Zealand rabbit was tested, a few malformed rabbit babies were obtained, and subsequently also some malformed monkeys—after years of tests [where researchers were constantly increasing the doses that were force-fed], hundreds of different strains and millions of animals used. But researchers immediately pointed out that malformations, like cancer, could be obtained by administration of practically any substance in high concentration, including sugar and salt, which will eventually upset the organism, causing trouble.[35]

### Birth Deformities on the Increase

As a result of the thalidomide tragedy, there has been a massive increase in the use of test animals but this has failed to prevent further deformities. On the contrary, the malformations have increased, and more than twenty years later, on 19 July 1983, a headline in *The New York Times* revealed: "Physical and Mental Disabilities in Newborns Doubled in 25 Years". Furthermore, it has recently been uncovered that every year more than a quarter of a million babies (1 in 12) are born with birth defects in the United States.[36]

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### Criticisms From Within

Because animal testing gives false and misleading data on the 'safety' and 'efficacy' of dangerous drug substances, many toxicologists and clinicians have expressed much criticism. To quote some of them:

> Even when a drug has been subjected to a complete and adequate pharmacologic investigation on several species of animals and found to be relatively non-toxic, it is frequently found that such a drug may show unexpected toxic reactions in diseased human beings. This has been known almost since the birth of scientific pharmacology.[37]
>
> (Dr E. Marshall, 1932, Baltimore.)

> ...most experts considered the modern toxicological routine procedure a wasteful endeavour in which scientific inventiveness and common sense have been replaced by a thoughtless completion of standard protocols.[38]
>
> (Professor G. Zbinden, World Health Organisation toxicologist.)

> Normally, animal experiments not only fail to contribute to the safety of medications, but they even have the opposite effect.[39]
>
> (Professor Kurt Fickentscher, 1980, of the Pharmacological Institute of the University of Bonn, Germany.)

### Animal Testing Gives Hints, Indications?

In support of animal testing, vivisectionists say: "We don't expect final answers from animal experiments, but just hints, indications, which encourage us to continue in a particular direction." This is, of course, sheer nonsense. Professor Pietro Croce explains:

> But what's an indication? An approximate information, merely orientative. And as the compass card shows, an orientation can point in the right direction, of which there is only one, or to one of the many wrong directions. And an animal experiment only very rarely points to the right direction, and when it does, it is due to coincidence, and at any rate verifiable only after the fact. Experimenting on animals to do medical research is like playing roulette.[40]

### How Should Drugs Be Tested?

Vivisectionists would have the public believe that animal testing is an essential part of drug testing and evaluation, and that these tests cannot be dispensed with. This is also nonsense, as true scientific methods that are accurate and reliable are available and in current use.

Drug testing and evaluation should include: the use of human tissues, cells and organs (*in vitro* cultures);[41] chromatography and mass spectrometry (which separate drug substances at their molecular level to identify their properties);[42] quantum pharmacology (using quantum mechanics to understand the molecular structure of chemicals);[43] properly carried-out human clinical trials;[44] and thorough reporting of drug side-effects by post-market surveillance.[45] The Ames test used in conjunction with *in vitro* tests is very effective in determining teratogenic and carcinogenic (cancer-causing) properties of substances.[46]

### Why Do Drug Companies Use Animal Tests?

Although the previously methods have a demonstrated proven worth, drug companies still insist on using misleading animal tests, because they argue that government regulations demand them. But why would they?

Bearing in mind the drug companies' criminal reputation in fraudulent drug testing and other illegal activities, with the collaboration of corrupt government and medical officials (as demonstrated by

Ruesch and Braithwaite, among others), the following analysis by Hans Ruesch comes as no surprise:

> **It is not only scandalous but also tragic that the Drug Trust is permitted to flood the market with its products on the grounds that they have been thoroughly tested for effectiveness and safety on animals, and that the Health Authorities, meaning the Government, abet this deception, which is nothing but confirmed fraud. For both sides are well aware that animal tests are fallacious and merely serve as an alibi—an insurance against the day when it is no longer possible to conceal the disastrous side effects of a drug. Then they can say that "all the required tests have been made"—that they have obeyed the Law.**
>
> But they don't say that they themselves have imposed those laws, because the Lawmaker has no choice in all medical questions but to submit to the dictates of the 'medical experts'. And who are they? Agents of the Chemo-Medical Syndicate, whose links to the Health Authorities are so close that they usually overlap. So they, and no one else, impart binding orders to that mysterious and omnipotent individual, identified anonymously as 'The Lawmaker'. [Emphasis added.][47]

To back his conclusions, Hans Ruesch has assembled massive damning evidence against the perpetrators of the phoney drug-testing fraud. This has been well-documented in his book *Slaughter of the Innocent*, and its sequel, *Naked Empress or The Great Medical Fraud* (1992). The documentary film, *Hidden Crimes* [48] (1986), which is based on Hans Ruesch's books and is produced by Javier Burgos, gives a visual account of the vivisection fraud.

Ruesch cited a criminal trial involving Chemie Grunenthal, the German manufacturer of thalidomide. They were incriminated for having marketed a harmful drug. Writes Ruesch:

> In December 1970, the longest criminal trial in Germany's judicial history—two and a half years, 283 days in court—ended with the acquittal of Chemie Grunenthal, **after a long line of medical authorities had testified that the generally accepted animal tests could never be conclusive for human beings.** This was unprecedented, for the testimonies came from an impressive array of individuals whose careers and reputations were practically built on animal experimentation...[49]

**If drugs were tested properly using true scientific methods, the vast majority of them would not be allowed onto the market ...**

Another example to illustrate the above point: Ruesch cites the case of Opren (the arthritis drug responsible for a number of deaths), as reported in the 12 February 1983 issue of Britain's *Economist*:

> The Labour member of parliament, Mr Jack Ashley, is campaigning against the refusal of Eli Lilly [drug company] to pay compensation to the families of Opren's victims. **Eli Lilly says that it complied with all pre-marketing testing requirements and cannot therefore be held liable through negligence.** [Emphasis added.][50]

### Doctors Agree: Vivisection is Scientific Fraud

The following statements from doctors, not bound to commercial interests, contribute to the real motives behind the vivisectionists' methods of drug testing:

> Results from animal tests are not transferable between species, and therefore cannot guarantee product safety for humans... In reality these tests do not provide protection for consumers from unsafe products but rather are used to protect corporations from legal liability.[51]
>
> (Dr Herbert Gundersheimer, 1988, Baltimore, Maryland.)

> Toxicologists are...pursuing an illusion of safety using animals to fulfil political and legal obligations. As if to confirm our suspicions, some drugs are marketed and clinical procedures undertaken despite 'failing' animal tests!
>
> But if animal tests are sometimes ignored, they can also be used to imply certain advantages of a company's new product over existing drugs...
>
> On the other hand, the fact that animal tests are misleading can form the basis of a company's defence against claims about one of its products...
>
> **So, if animal experiments are misleading, they are at least flexible: they can be deemed inapplicable when necessary, ignored when convenient and used to imply important advantages over competing products.** [Emphasis added.][52]
>
> (Dr Robert Sharpe, in *The Cruel Deception*, 1988.)

> Another basic problem which we share as a result of the regulations and the things that prompted them is an unscientific preoccupation with animal studies. Animal studies are done for legal reasons and not for scientific reasons. The predictive value of such studies for man is often meaningless—which means our research may be meaningless.[53]
>
> (Dr James Gallagher, 1964, Director of Medical Research, Lederle Laboratories, US.)

> There are many ways of producing 'irrefutable' facts in support of any argument, using different kinds of animals: one just has to choose the right one. For example:
>
> Do we want to show that Amanita phalloides is an excellent edible toadstool? Then we have only to feed it to the rabbit...
>
> Do we want to discourage people from eating parsley? Let us give it to the parrot, which will probably be found lying stone-dead under its perch the next morning.
>
> Should we wish to rule out penicillin as a therapeutic drug, we have only to give it to the guinea-pig which will be dead in a couple of days....
>
> If we wish to convince the consumers of tinned food that botulin poison is harmless, let us give it to the cat and it will lick its lips. Let us give it instead to the cat's traditional prey, the mouse, and it will die as if struck by lightning....
>
> If we need to show that Vitamin C is useless, we withhold it from the diet of the most readily available animal: the dog, the rat, the mouse, the hamster... they will continue to thrive because their bodies produce Vitamin C of their own accord. But let us not eliminate it from the diet of guinea-pigs, primates or humans, or they will die of scurvy...
>
> **To sum up, one has only to know how to choose the proper animal species to obtain the desired results... This is a kind of science which one can knead like dough.** The trouble comes in believing that with dough one can produce health for human beings. [Emphasis added.][54]
>
> (Professor Pietro Croce in *Vivisection or Science—A Choice to Make*, 1991. From 1952 to 1982 Croce was head of the laboratory of microbiological, pathological anatomy and chemical analysis at the Research Hospital L. Sacco of Milan, Italy.)

Relying on animal tests means that new products which are thought to be safe are mass-marketed far too quickly and are prescribed by general practitioners and hospital doctors for thousands or even millions of patients without ever being properly assessed. It is hardly surprising that when problems occur—as they do all too frequently these days—they occur on a massive scale. Animal experiments allow drug companies to mass-market new drugs without testing them to see if they are safe and they encourage complacency among prescribing doctors who are not as alert for side-effects as they should be because they have been told that the drugs they are prescribing are safe.

The consequence of our reliance on animal testing is that new and untried drugs and procedures are being tested on vast num-

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bers of people simply so that those making those drugs or pieces of equipment can make massive profits as quickly as possible.[55]

(Dr Vernon Coleman, 1991, author of a number of books on health and medicine, UK.)

The great majority of perinatal toxicological studies seem to be intended to convey medico-legal protection to the pharmaceutical houses and political protection to the official regulatory bodies, rather than produce information that might be of value in human therapeutics.[56]

(Professor D. Hawkins, 1983, Prof. of Obstetric Therapeutics at the Institute of Obstetrics and Gynaecology, and Consultant Obstetrician and Gynaecologist at Hammersmith Hospital, UK.)

The extensive animal reproduction studies to which all new drugs are now subjected are more in the nature of a public relations exercise than a serious contribution to drug safety... The illogicality of the situation is demonstrated by the continued use of well-established drugs which are known to be teratogenic in some mammalian species (e.g. aspirin, penicillin/streptomycin, cortisone). Conversely a new drug which comes through its animal reproductive studies with flying colours may nevertheless be teratogenic in man.[57]

(Professor R.W. Smithells, 1980, Prof. of Paediatrics and Child Health at the University of Leeds and a former member of the Committee on Safety of Medicines.)

The virtue of animal model systems to those in hot pursuit of the federal dollars is that they can be used to prove anything—no matter how foolish, or false, or dangerous this might be. There is such a wide variation in the results of animal model systems that there is always some system which will 'prove' a point. Fraudulent methods of argument never die and rarely fade away. They are too useful to promoters...[58]

(Dr Irwin Bross, 1982, former Director of the largest cancer research institute in the world, the Sloan-Kettering Institute, then Director of Biostatics, Roswell Memorial Institute, Buffalo, NY.)

The richest earnings occur when a new variety of a drug is marketed before competing drugs can be discovered. Under this system it is impracticable to do tests extending over a long period to establish the range of usefulness and potential dangers from toxicity... Thus after extensive laboratory tests on toxicity and pharmacological properties, but sometimes with a minimum of clinical trial, a drug may be marketed.[59]

(Dr William Bean, 1957, of the Iowa State University in his testimony to the Kefauver Committee.)

### Conclusion on Drug Testing

The inescapable conclusion is that drug companies choose animal tests over scientific methods because of the utter unreliability of animal tests. Because each animal species is unique in its physiological, biochemical, histological, morphological and other characteristics, and consequently reacts differently to substances, drug companies can produce results favourable to their interests by simply choosing the appropriate species.

If their product is harmless, fine, money rolls in. If it's harmful, no problem, accusations are disposed of on the grounds that it was tested and found to be 'safe' on animals.

If drugs were tested properly using true scientific methods, the vast majority of them would not be allowed onto the market because their harmfulness and ineffectiveness would be all too apparent. The constant stream of new drugs would slow to a trickle and within a few years most drug companies would go bankrupt.

### Drugs Are Poisons

The problem is that virtually all drugs are toxic to some degree, and as Eli Lilly once said, "a drug without side-effects is no drug

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at all."[60] No drug can be pinpointed to affect only the organ it is designed to treat, and most drugs have broad effects and some affect virtually every organ system in the body.[61]

Drugs are toxic because they are generally composed of artificial chemical compounds that have been synthesised in the laboratory.[62] In the past, before drugs became big business, nearly all medicines were composed of natural plant-derived ingredients that were far safer than today's drugs. Unfortunately, the drug companies today choose to chemically synthesise the ingredients instead, because they are cheaper to produce and can be patented, giving the companies monopoly rights on their sales.[63]

For some insight into the toxic nature of the next drug your doctor tries to prescribe for you, the authors recommend that you ask him or her to look up the drug for you in their copy of *MIMS Annual* or *MIMS* (bi-monthly).[64] These books, which doctors have at their disposal, give disturbing details on the toxic effects of individual drugs. You will discover that your doctor would more than likely be reluctant, because he or she knows that after seeing the details for yourself you would most probably refuse the drug. However, be warned: the information in *MIMS* is only what the drug companies supply and is not a true account of how dangerous these chemical substances really are.

**How Many Drugs Do We Need?**

Already over 30 years ago, Dr Walter Modell of Cornell University's Medical College, whom *Time* had described as "one of America's foremost drug experts", wrote in *Clinical Pharmacology and Therapeutics*:

> When will they realize that there are too many drugs? No fewer than 150,000 preparations are now in use. About 15,000 new mixtures and dosages hit the market each year, while about 12,000 die off... We simply don't have enough diseases to go around. At the moment the most helpful contribution is the new drug to counteract the untoward effects of other new drugs.[65]

Since 1961, the number of drug preparations marketed worldwide has increased to 205,000 with a proportional rise in new maladies.

Further, Ruesch reveals:

> In 1980, the Geneva-based World Health Organisation (WHO) published a list of 240 drugs that were considered "essential" or sufficient for Third World needs. Since the Third World's health has been touted as being very much in need of Western help, the 240 drugs should more than suffice for Western populations as well.

Considering WHO's report, how come have an estimated 205,000 drugs and combinations thereof been produced—most of which have long since been withdrawn?...

On 14 October 1981 the Swiss weekly *Weltwoche* reported that UNIDO (United Nations Industrial Development Organisation) had set up in collaboration with WHO a list of merely 26 drugs that were considered indispensable for the Third World...

The UNIDO report emphasized that of the 26 "indispensables", 9 should have special priority.

And which drug topped the list of these 9 that were considered even more indispensable than all the other indispensables? Acetylsalicylic acid, meaning our good old Aspirin, which was discovered almost 100 years ago and has proved itself less harmful than most other drugs. Perhaps because it is one of the few still in use today that had not been developed by animal tests?

Some people think that even the list of 9 more indispensable than others is too long.[66]

**Some Fraudulently Tested Drugs That Injured and Killed**

Paracetamol (painkiller)—1,500 people had to be hospitalised in Great Britain in 1971.

Orabilex—caused kidney damages with fatal outcome.
MEL/29 (anti-hypertensive)—caused cataracts.
Methaqualone (hypnotic)—caused severe psychic disturbances leading to at least 366 deaths, mainly through murder or suicide.
Thalidomide (tranquilliser)—caused 10,000 malformed children.
Isoproterenol (asthma)—caused 3,500 deaths in the 'sixties.
Stilboestrol (prostate cancer)—caused cancer in young women.
Trilergan (anti-allergic)—caused viral hepatitis.
Flamamil (rheumatism)—caused loss of consciousness.
Eraldin (heart medication)—caused severe eye and digestive tract damage, and many deaths.
Phenformin (diabetes)—caused 1,000 deaths annually until withdrawn.
Atromid S (cholesterol)—caused deaths from cancer, liver, gall bladder and intestinal disease.
Valium (tranquilliser)—addictive in moderate doses.
Preludin & Maxiton (diet pills)—caused serious damage to the heart and the nervous system.
Nembutal (insomnia)—caused insomnia.
Pronap & Plaxin (tranquillisers)—killed many babies.
Phenacetin (painkiller)—caused severe damages to kidneys and red blood corpuscles.
Amydopyrine (painkiller)—caused blood disease.
Marzine (nausea)—damaged children.
Reserpine (anti-hypertensive)—increased risks of cancer of the brain, pancreas, uterus, ovaries, skin and women's breasts.
Methotrexate (leukaemia)—caused intestinal haemorrhage, severe anaemia and tumours.
Urethane (leukaemia)—caused cancer of liver, lungs and bone marrow.
Mitotane (leukaemia)—caused kidney damage.
Cyclophosphamide (cancer)—caused liver and lung damage.
Isoniazid (tuberculosis)—caused liver destruction.
Kanamycin (tuberculosis)—caused deafness and kidney destruction.
Chloromycetin (typhoid)—caused leukaemia, cardiovascular collapse and death.
Phenolphthalein (laxative)—caused kidney damage, delirium and death.
Clioquinol (diarrhoea)—caused blindness, paralysis and death.
DES (prevent miscarriage)—caused birth defects and cancer.
Debendox (nausea)—caused birth defects.
Accutane (acne)—caused birth defects.
Kanamycin (tuberculosis)—caused deafness and kidney destruction.

The preceding list, taken from *Vivisection: Science or Sham*[67] (by Dr Roy Kupsinel, 1990), and *Naked Empress*,[68] is just a very small sample of a far greater number of therapeutic disasters that have taken place.

In fact, the therapeutic disasters, steadily on the increase today, did not exist before the imposition of the safety-tests done on animals. They are a direct result of widespread animal experimentation.[69]

(Hans Ruesch in *Naked Empress*, 1992.)

## Vivisection—The Distorted Issue

The issue of animal experimentation has been a very contentious one for well over a century—since the time the French physiologist Claude Bernard (1813-1878) founded the modern vivisectionist method.

Defenders of animal experimentation, through their aggressive campaigns with the help of the industry-beholden media, have largely succeeded in convincing the public that vivisection is responsible for any medical progress and that the only possible objection is solely based on animal welfare.

On the contrary, medical historians such as Hans Ruesch,[70] Dr Beddow Bayly,[71] Dr Robert Sharpe[72] and Dr Brandon Reines,[73] to

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name a few, have repeatedly demonstrated that important discoveries were made through human clinical research, observations of patients and human autopsies among other human-based research methodologies, and that vivisectionists have distorted medical history in their favour. Animal experimentation has served primarily to 'prove' in animals what had already been demonstrated in people.

Also, contrary to what the proponents of vivisection would have the public believe, the stongest objection to vivisection has been from the medical and scientific community. The book, *1000 Doctors (and many more) Against Vivisection* ™ (1989), by Hans Ruesch, highlights this fact. *1000 Doctors* is a compilation of an impressive collection of anti-vivisection statements made by doctors and scientists from around the world. The professional verdicts that start as far back as 1824, are a reminder of the fact that there have always been members of the scientific and medical profession strongly opposed to vivisection on scientific and medical grounds.

With today's medical research being heavily based on fraudulent animal experimentation, is it any wonder that diseases remain uncured and are on the increase: diseases such as cancer, diabetes, heart disease, birth defects, arthritis, muscular dystrophy, leukaemia, all kinds of mental disease, Alzheimer's, and the latest tragedy, AIDS. ∞

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